Page 2

REMARKS

Claims 1-39 were pending in the application. Claims 12, 13, 37, and 38 are cancelled. Claims 1-11, 14-36, and 39 are amended. Upon entry of this Preliminary Amendment claims 1-11, 14-36, and 39 will be pending in the application and are presented for examination. The new claims do not introduce any new matter, and support for them can be found in the cancelled claims.

Date: June 5, 2003 Reg. No. 45,238

Tel. No. (617) 310-8176

Fax No. (617) 248-7100

Respectfully submitted,

Gerald E. Worth

Attorney for Applicants

Testa, Hurwitz, & Thibeault, LLP

High Street Tower 125 High Street Boston, MA 02110

Page 3

Marked-Up Copy of Amended Claims

1. (Amended) A [medical device] ureteral stent for assisting in the drainage of fluid from a body cavity comprising:

an elongated member comprising a distal end and a proximal end and defining a first lumen extending therebetween; and

a valve disposed at the proximal end of the elongated member, the valve comprising:

a tube defining a second lumen in fluid connection with the first lumen, the tube comprising a first end connected to the proximal end of the elongated member, and a socket;

a shaft at least partially disposed in the socket; and
a stopper connected to the shaft that occludes the second lumen when
exposed to retrograde pressure.

- 2. (Amended) The [device] <u>ureteral stent</u> of claim 1, wherein the shaft is fixed in the socket.
- 3. (Amended) The [device] <u>ureteral stent</u> of claim 2, wherein the stopper comprises a deformable film.
- 4. (Amended) The [device] <u>ureteral stent</u> of claim 1, wherein the shaft is axially translatable in the socket.
- 5. (Amended) The [device] <u>ureteral stent</u> of claim 4, wherein the shaft is tapered inwardly toward the stopper and the socket is tapered inwardly toward the stopper, both preventing complete removal of the shaft from the socket.
- 6. (Amended) The [device] <u>ureteral stent</u> of claim 4, wherein the valve further comprises a spring disposed in the socket that is biased to open the valve in the absence of a retrograde pressure.

Al

Page 4

- 7. (Amended) The [device] ureteral stent of claim 1, wherein the tube further defines at least one additional lumen in fluid connection with the first lumen, wherein the second lumen and the additional lumen are disposed about the periphery of the socket.
- 8. (Amended) The [device] <u>ureteral stent</u> of claim 1, wherein the stopper comprises a substantially circular surface and the shaft is attached to the stopper at the center of the circular surface.
- 9. (Amended) The [device] <u>ureteral stent</u> of claim 1, wherein the stopper further comprises a lip disposed about the periphery of a distal surface of the stopper.
- 10. (Amended) The [device] <u>ureteral stent</u> of claim 1, wherein the stopper comprises a substantially hemispherical surface and the shaft is attached to the stopper at the center of the hemispherical surface.
- .11. (Amended) The [device] <u>ureteral stent</u> of claim 1, wherein the stopper comprises a substantially wedge-shaped section.
- 12. (Cancelled)
- 13. (Cancelled)
- 14. (Amended) The [device] <u>ureteral stent</u> of claim 1, further comprising a retention structure extending distally from the distal end of the elongated member.
- 15. (Amended) The [device] <u>ureteral stent</u> of claim 14, wherein the retention structure further defines a passageway extending between an opening and the first lumen.
- 16. (Amended) The [device] <u>ureteral stent</u> of claim 1, further comprising a retention structure extending from the stopper.
- 17. (Amended) The [device] <u>ureteral stent</u> of claim 16, wherein the retention structure is a lip disposed about a periphery of the stopper having a perimeter wider than the proximal end of the elongated member.



Page 5

18. (Amended) A valve for preventing reflux of fluids in a [medical device] ureteral stent comprising:

a tube defining a lumen having a first end and a second end, and a socket;

a shaft at least partially disposed in the socket; and

a stopper attached to the shaft that occludes the lumen when exposed to retrograde pressure.

- 19. (Amended) The [device] valve of claim 18, wherein the shaft is fixed in the socket.
- 20. (Amended) The [device] valve of claim 19, wherein the stopper comprises a deformable film.
- 21. (Amended) The [device] valve of claim 18, wherein the shaft is axially translatable in the socket.
- 22. (Amended) The [device] valve of claim 21, wherein the shaft is tapered inwardly toward the stopper and the socket is tapered inwardly toward the stopper, both preventing complete removal of the shaft from the socket.
- 23. (Amended) The [device] valve of claim 18, wherein the valve further comprises a spring disposed in the socket that is biased to open the valve in the absence of retrograde pressure.
- 24. (Amended) The [device] valve of claim 18, wherein the tube further defines at least one additional lumen, wherein the first lumen and the additional lumen are disposed about the periphery of the socket.
- 25. (Amended) The [device] valve of claim 18, wherein the stopper comprises a substantially circular surface and the shaft is attached to the stopper at the center of the circular surface.



Page 6

- 26. (Amended) The [device] valve of claim 18, wherein the stopper further comprises a lip disposed about the periphery of a distal surface of the stopper.
- 27. (Amended) The [device] <u>valve</u> of claim 18, wherein the stopper comprises a substantially hemispherical surface and the shaft is attached to the stopper at the center of the hemispherical surface.
- 28. (Amended) The [device] valve of claim 18, wherein the stopper comprises a substantially wedge-shaped section.
- 29. (Amended) A method of assisting the drainage of fluid from a body cavity, the method comprising:

providing a [medical device] ureteral stent comprising:

an elongated member comprising a distal end and a proximal end and defining a first lumen extending therebetween; and

a valve disposed at the proximal end of the elongated member, the valve comprising:

a tube defining a second lumen in fluid connection with the first lumen, the tube comprising a first end connected to the proximal end of the elongated member, and a socket;

a shaft at least partially disposed in the socket; and

a stopper connected to the shaft that occludes the second lumen when exposed to retrograde pressure; and

inserting said device into a ureter.

30. (Amended) A [medical device] <u>ureteral stent</u> for assisting in the drainage of fluid from a body cavity, comprising:

an elongated member comprising a distal end and a proximal end and defining a first lumen extending therebetween;

a seat defined by the elongated member;

a shoulder defined by the elongated member proximal to the seat; and

h!

Page 7

a ball disposed in the elongated member between the seat and the shoulder that occludes the first lumen when exposed to retrograde pressure.

- 31. (Amended) The [device] <u>ureteral stent</u> of claim 30, wherein the elongated member defines at least one slot between the seat and the shoulder.
- 32. (Amended) The [device] <u>ureteral stent</u> of claim 30, further comprising a retention structure defining a second lumen in fluid connection with the first lumen.
- 33. (Amended) The [device] <u>ureteral stent</u> of claim 32, wherein the shoulder is defined by an interface between the elongated member and the retention structure.
- 34. (Amended) The [device] <u>ureteral stent</u> of claim 32, wherein the retention structure has a pigtail shape.
- 35. (Amended) The [device] <u>ureteral stent</u> of claim 30, comprising a retention structure extending from the distal end of the elongated member.
- 36. (Amended) The [device] <u>ureteral stent</u> of claim 35, wherein the retention structure further defines a passageway extending between an opening and the first lumen.
- 37. (Cancelled)
- 38. (Cancelled)
- 39. (Amended) A method of preventing reflux of fluids in a [medical device] <u>ureteral</u> stent the method comprising:

providing a [medical device] ureteral stent comprising:

an elongated member comprising a distal end and a proximal end and defining a first lumen extending therebetween,

a seat defined by the elongated member,

a shoulder defined by the elongated member proximal to the seat,

and



Page 8

a ball disposed in the elongated member between the seat and the shoulder that occludes the first lumen when exposed to retrograde pressure; and inserting said device into a ureter.

